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Marilyn Kelso < Marilyn. Kelso@tdh.state.tx.us>

To:

"Brenda Usilton (E-mail)" <bgu@nrc.gov>

Date:

5/14/04 4:29PM

Subject:

Comments on Restructuring the Teletherapy and Brachytherapy Course

The following comments are from the Texas Department of Heatlh, Bureau of Radiation Control concerning Restructuring the Teletherapy and Brachytherapy Course:

"In considering the important parts of the Teletherapy and Brachytherapy course, NRC should concentrate more on the modalities that are most in use and have radiation safety and licensing concerns:

- 1) Licensing and inspection guidance for LDR and HDR brachytherapy and gamma knife
- 2) 10 CFR 35.1000 radiation safety concerns (new technologies)
- 3) Medical events involving teletherapy and brachytherapy/lessons learned

There are several areas that could be deleted or discussed in much less detail in order to give time for the areas delineated above:

Clinical management of the patient for both teletherapy and brachytherapy

Dosimetry and calibration of teletherapy units

Eliminating the patient management information and most of the dosimetry would seem reasonable. Most, if not all, class participants are regulatory personnel who really don't need to be concerned with patient management. Only in medical event situations do regulatory staff get involved with dosimetry issues. Therefore, the basic dosimetry calculations should remain to enhance the regulators' understanding of the problems involved in therapeutic administration of radiation.

Thanks for the opportunity to comment."

"My comments are that it is time to restructure the course, however, there still needs to be some mention of the teletherapy portion that should include disposition issues related to the teletherapy heads, export by vendor licensees as well as information regarding use and radiation safety related to teletherapy. I think there are still a few of these in operation around the state, so the information would be helpful."

"Demaris, Curt" < Curt. Demaris @ DOH.WA.GOV>

To:

"bgu@nrc.gov" <bgu@nrc.gov>

Date:

5/13/04 5:35PM

Subject:

Tele/Brachy Restructure Comments

Dear Brenda:

Please consider this the response for the state of Washington to your call for suggested improvements of the tele/brachy nuclear medicine course.

First, we all completely agree with the prevailing opinion that the Co-60 teletherapy info is no longer germane, and would delete this entirely.

Second, we all also agree with the inclusion of the newer modalities, e.g. "IVB, HDR, LDR, and Gamma Knife" for sealed source therapy, as well as addressing use of liquid therapy beta-emitters and the currently-in-vogue high dose/Bexxar I-131 therapy, including rationale and calculations for realistic patient release.

Finally, we all agree that methods of inspection and licensing for these modalities would certainly be worthwhile for such a class.

On a final and personal note, I continue to call for guidance regarding nuclear pharmacy, both in reviewing and writing the licenses, and for onsite compliance inspections. So far, I have met with absolutely no success.

Thank you for the opportunity to comment. Let us know if we can be of further service.

C. DeMaris Medical Licensing

CC:

"Scroggs, Arden" < Arden. Scroggs @ DOH.WA.GOV>

"Julie Felice" <JFELICE@utah.gov>

To: Date: <BGU@nrc.gov> 5/3/04 7:00PM

Subject:

RE: STP-04-029

Brenda:

I remember hearing the instructor talk about how this course needed to be revised when I attended this training course in 2000.

What I liked least about the course:

1) In Utah, we had no teletherapy machines, at the time I took the course.

2) Too much time was spent on teletherapy machines. (This seemed irrelevent at the time since there are no longer any teletherapy machines in Utah).

3) Too much emphasis was placed on teletherapy and not enough time was spent on High Dose Remote Afterloaders and new technologies. (What I really needed the most was information on HDRs and we only spent approximately 1/2 of a day).

Regarding what should be included:

I believe it would be helpful to focus on the following:

- 1. Brachytherapy (temporary and permanent implants) and the radiation safety issues, regulatory concerns, and other special concerns for this modality;
- 2. Operation and use of HDR, MDR, LDR, PDR devices, necessary calibration checks, periodic spot checks, radiation safety issues, regulatory concerns, and other special concerns for these devices;
- 3. Operation and use of Gamma Sterotactic Radiosurgery Units necessary calibration checks, periodic spot checks, radiation safety issues, regulatory concerns, and other special concerns for these devices;
- 4. Operation and use of the various IVB devices, necessary calibration checks, periodic spot checks, radiation safety issues, regulatory concerns, and other special concerns for these devices;
- 5. New uses and modalities as they are developed and the radiation safety issues, regulatory concerns, and other special concerns for these devices. For example: Liquid Brachytherapy Sources and Devices (Gliasite), Microsphere Brachytherapy Sources (TheraSphere and SIRSphere Yttrium-90 Microspheres), Nucletron seedSelectron® and Nucletron FIRST* System, etc.
- 6. It would also be helpful if general information regarding treatment planning, dosimetry, fractions, etc. are covered. Generally inspectors are not able to inspect areas that are under the purview of the "practice of medicine," therefore, spending two days on the nuts and bolts of this type of information may help the inspector understand what a patient goes through and the process that doctors take, but it doesn't necessarily aide them on the regulatory end of things.

Respectfully,

Julie Rupp Felice, CPM
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"Gwyn Galloway" <ggalloway@utah.gov>

To: Date: <BGU@nrc.gov> 4/30/04 5:16PM

Subject:

Teletherapy and Brachytherapy Course

Brenda,

I concur with many of the comments made and they are about the same comments I made when I took the course years ago. In restructuring the course, I believe it would be helpful to focus on the following:

- 1. Brachytherapy (temporary and permanent implants) and the radiation safety issues, regulatory concerns, and other special concerns for this modality;
- 2. Operation and use of HDR, MDR, LDR, PDR devices, necessary calibration checks, periodic spot checks, radiation safety issues, regulatory concerns, and other special concerns for these devices;
- 3. Operation and use of Gamma Sterotactic Radiosurgery Units necessary calibration checks, periodic spot checks, radiation safety issues, regulatory concerns, and other special concerns for these devices;
- 4. Operation and use of the various IVB devices, necessary calibration checks, periodic spot checks, radiation safety issues, regulatory concerns, and other special concerns for these devices;
- 5. New uses and modalities as they are developed and the radiation safety issues, regulatory concerns, and other special concerns for these devices. For example: Liquid Brachytherapy Sources and Devices (Gliasite), Microsphere Brachytherapy Sources (TheraSphere and SIRSphere Yttrium-90 Microspheres), Nucletron seedSelectron® and Nucletron FIRST* System, etc.
- 6. It would also be helpful if general information regarding treatment planning, dosimetry, fractions, etc. are covered. Generally inspectors are not able to inspect areas that are under the purview of the "practice of medicine," therefore, spending two days on the nuts and bolts of this type of information may help the inspector understand what a patient goes through and the process that doctors take, but it doesn't necessarily aide them on the regulatory end of things.

These are just a few thoughts. If you have any questions regarding the above, please let me know.

Gwyn Galloway, Health Physicist <ggalloway@utah.gov>

"George Johns" <George.Johns@state.mn.us>

To: Date: <bgu@nrc.gov>
4/28/04 5:25PM

Subject:

Comments on Teletherapy and Brachytherapy Course

Hello, Brenda.

I checked to verify that you are the one indicated as recipient for the comments, so...

Generally, the comments are correct. There is a disproportional emphasis on teletherapy. However, that is a function of the ebbs and flows of medicine. Gamma Stereotactic Radiosurgery, another external beam application, has not managed to flourish.

There was a suggestion to include intervascular brachytherapy. While I have been buried by requests for that application, indications are that the procedure is being made obsolete by chemical stints. Hospitals that were doing several IVB procedures a week now indicate that they are down to one a month or less. It would appear to be inappropriate to devote significant class time to this topic.

I would suggest that rather than focus on a particular device, it might be better to focus on the expectations for external beam therapy and brachytherapy. In other words, address the requirements more generically so that, as new protocols develop, there will be an understanding of the safety aspects that should be reviewed during licensing and inspection.

Although the NRC does not regulate accelerators, from an Agreement State's viewpoint, there should be training in that area. Frankly, there are very few opportunities to obtain that training.

Regards,

George F. Johns, Jr. Radiation Control Unit Minnesota Department of Health

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CC: "Linda Bruemmer" <Linda.Bruemmer@state.mn.us>, "Timothy Donakowski" <Timothy.Donakowski@state.mn.us>